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TITLE: Safety and Efficacy of the BrainPort V100 Device in Individuals Blinded by Traumatic Injury

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CONTRACTING ORGANIZATION: Wicab, Inc.
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14. ABSTRACT

This study is a prospective, single-arm, multicenter clinical investigation. The aim of this study is to evaluate the functional performance of the BrainPort® V200 device, a non-surgical, FDA approved, sensory substitution system, in persons who are profoundly blind due to a traumatic injury (cortical or ocular). The device, which provides visual information via electrotactile stimulation on the tongue, is designed to enhance independence in performing activities of daily life. Nine out of the 20 projected participants have been enrolled across study sites. Participants have received ten hours of device training and have taken the device home to use in their everyday environments for the next 12 months. Functional performance measures of object identification, place setting identification, orientation and mobility, and word identification were assessed at baseline and post-device training. Follow-up assessments will be completed at 3, 6, 9, and 12 months. The psychosocial impact of assistive devices and general self-efficacy were assessed at baseline and will be measured a second time at the end of the study. Device-related adverse events will be reported throughout the study to evaluate the risks associated with the BrainPort V200. The remaining 11 participants have been recruited and will be enrolled within the next quarter.

15. SUBJECT TERMS
BrainPort, V100, V200, blindness, visual impairment, assistive device, assistive technology, visual aid, non-surgical visual prosthetic, sensory substitution

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TABLE OF CONTENTS

1. INTRODUCTION:

The BrainPort V200 device is a wearable, non-surgical, FDA approved, prosthetic device intended for people who are profoundly blind. The BrainPort V200 translates images captured by a digital camera into electrotactile stimulation presented on the user's tongue to perceive shape, size, location, and motion of objects within the environment. The purpose of this study is to evaluate the safety and functional performance of the BrainPort V200 in individuals who have been medically documented as blind, light perception or worse, due to a traumatic injury (cortical or ocular).

2. KEYWORDS:

BrainPort, V100, V200, blindness, visual impairment, assistive device, assistive technology, visual aid, non-surgical visual prosthetic, sensory substitution

3. ACCOMPLISHMENTS:

What were the major goals and objectives of the project?

The major goals of this research project are to evaluate the safety and effectiveness of the BrainPort V200 device in individuals who have been blinded by traumatic injury by enabling this population to use and evaluate the BrainPort V200 device in normal operational settings, including at home and in public places. An additional objective of this study is to explore the design and hardware requirements for a population with multiple disabilities (polytrauma). The aim is that the findings from this research will result in a proven assistive technology ready for rapid deployment to wounded warriors, veterans, and civilians who have been blinded by traumatic events.

What was accomplished under these goals?

Specific Aim 1: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc).

Subject Enrollment

To date 22, subjects have been recruited for the study across the three study sites (14 from Chicago Lighthouse, 7 from Lighthouse Guild, and 1 from Wicab, Inc.). Of these 22 subjects, 3 are veterans. Of these 22 subjects, a total of 9 have been enrolled into the study, completed training on the BrainPort V200, and are using the device independently in their own environment for a period of 12 months. The remaining 13 candidates have been pre-screened, meet the inclusion criteria, and are scheduled for in-clinic screening appointments through November, 2016 or until we meet our enrollment cap of 20 across study sites.

Subject Follow-Up

An online blog has been established on CafePress.com and subjects who have entered the home phase of the study have been invited to anonymously post comments on device usage, troubleshooting tips, and suggestions for device improvements. The site is monitored by the PI.

In the next reporting period, subjects will return to the study site for their first quarterly functional assessment.

Development of the BrainPort V200

The BrainPort V200 electronic and headset frame design were finalized during the 4th quarter. The headset frame design (plastic and silicone components) was completed and device hardware

and software were implemented. Device builds were initiated in September to meet the initial study subject enrollment date of September 14, 2015. To date, 16 devices have been fabricated: 6 for Chicago Lighthouse, 8 for NY Lighthouse Guild, and 2 for Wicab, Inc. internal use). All study personnel have been fully trained on how to use and provide training on the BrainPort V200 by Lead Engineer and Co-Principal Investigator, Rich Hogle.

Figure 1 shows a complete V200 unit.

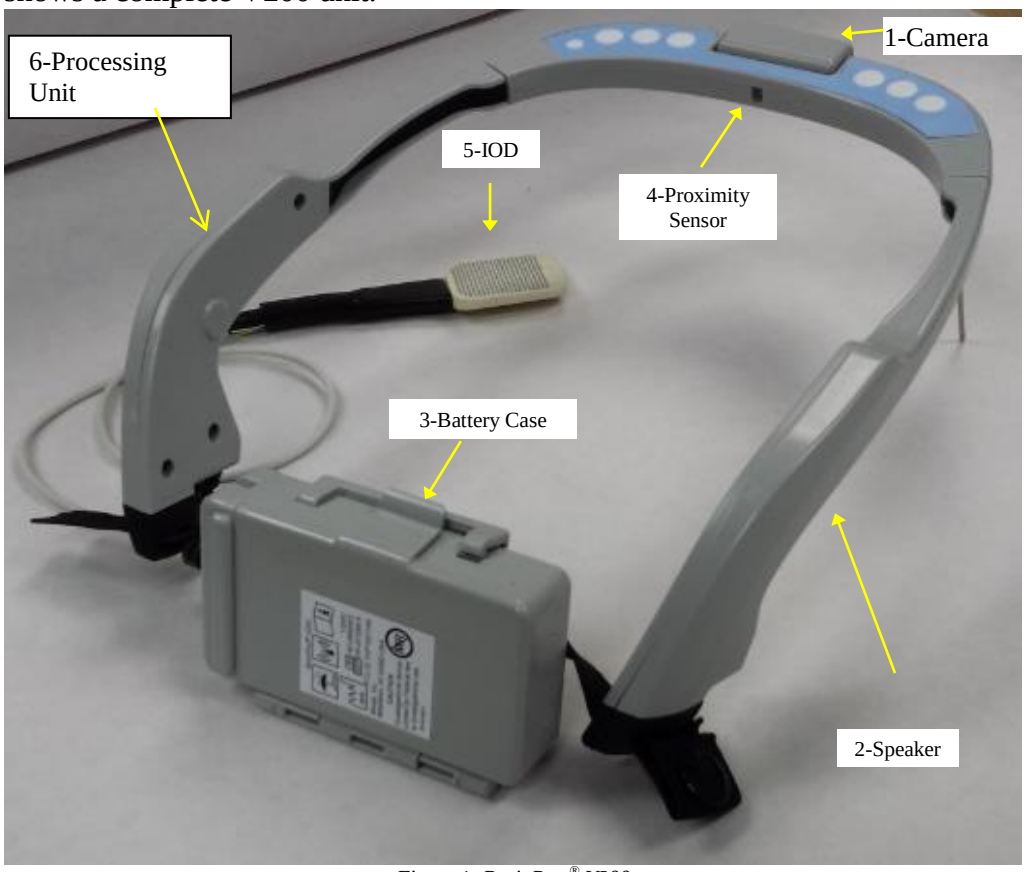


Figure 1: BrainPort® V200

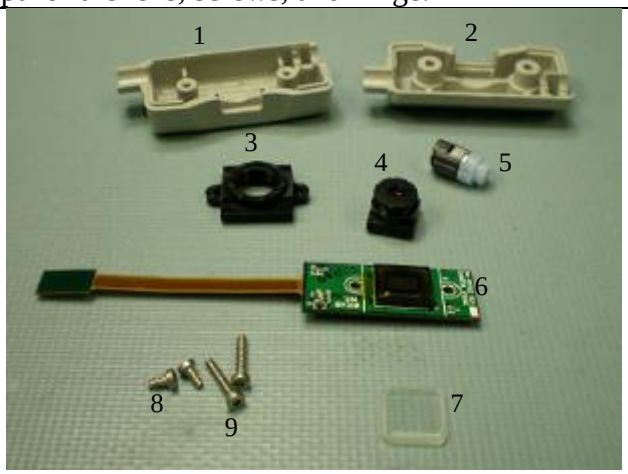
BrainPort® V200 Device Components

1.	Camera	Used to capture the scene in front of the wearer
2.	Speaker	Provides audio feedback
3.	Battery Case	Contains the rechargeable battery. Mounted on the rear of the headset with an adjustable strap
4.	Proximity Sensor	Detects when headset is being worn. The system will shut down if after several minutes if the headset is removed
5.	IOD	Contains the electrodes which present the stimulation patterns to your tongue
6.	Processing Unit	Embedded computer controlling and managing device activity

The headset frame components were injection molded with the majority of parts being fabricated with clear Makrolon (polycarbonate) tinted with ‘soft gray’ colorant. The arm inserts and strap holders are injection molded with black silicone rubber.

The following table shows the level of detail involved in both the design of the plastic housings, the components installed in those housings, and assembly of said parts.

In this example, the Camera Assembly is shown. Wicab designed and fabricated (contract manufacturing) each to the components except for the lens, screws, and hinge.

BrainPort V200 Camera Assembly	
1. DR-001237, Headset, Camera Top, V200C 2. DR-001238, Headset, Camera Bottom, V200C 3. DR-001212, Lens Holder, V200C 4. DR-001213, Camera Lens, V200C 5. DR-001171, Headset, Camera Hinge, V200 6. DR-001192, PCA, CAMERA, V200C 7. DR-001218, Camera Window, V200C 8. 18-8 Stainless Steel M1.59 × 0.6, 3mm—T5 (99397A009) 9. 18-8 Stainless Steel, Torx, M1.59 Size, 8mm (99397A022)	

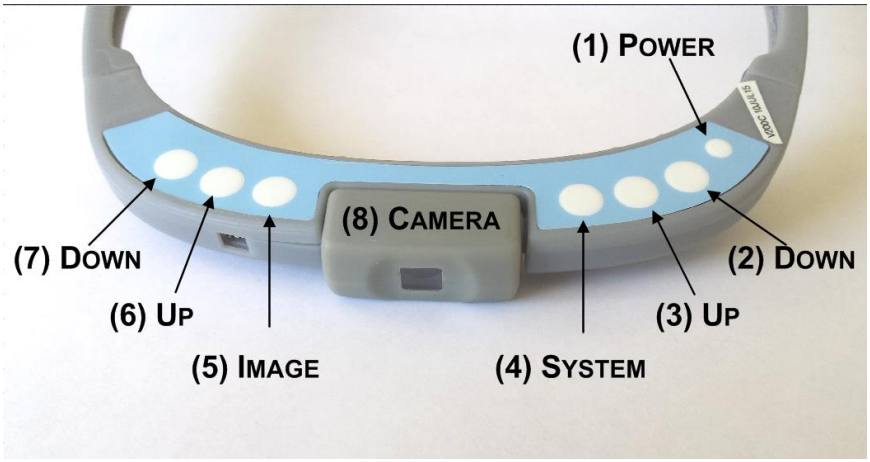
Description of BrainPort V200

Headset
The headset consists of the device controls, power pack, and a digital video camera that is mounted on an eyeglass-type frame. It may be worn by itself or optionally with an pair of glasses or sunglasses. The camera's field of view is user-controlled and varies from narrow to wide angle views. The Intra Oral Device (IOD) is permanently attached to the left earpiece by a cable.

Intra Oral Device (IOD)
The IOD (tongue electrode array) contains electrodes that act as "pixels" for the tongue. The flat side with the electrodes should be in contact with the front top surface of the tongue. The stimulus pattern on the electrode array corresponds to the scene captured by the camera (or to test patterns). There is one cable exiting the thin stem of the IOD that is permanently attached to the earpiece of the headset.

Battery Charger
A battery charger with factory instructions and two lithium-polymer rechargeable batteries are included.

User Controls
The User Controls are on the headset. The numbers in the descriptions refer to items in the figure below.



POWER (1)

Device on/off button. To turn the device on or off, press the button.

SYSTEM (4)

This button scrolls through the **SYSTEM** features. The **UP (3)** and **DOWN (2)** buttons next to **SYSTEM** selects the specific action for that feature. **SYSTEM** features are:

STATUS: Up/Down will cycle through following status reports, announcing the information at each stop

- the battery charge level,
- Lighting condition detected by the device
- the software version on the device.

VOLUME: Up/Down will cycle through the following volume levels, changing the volume to the currently selected feature

- mute,
- low,
- medium
- high.

Note that the mute function will not mute the status function.

WIFI: Use the Up or Down buttons to enable or disable the WiFi. Disabling the WiFi will help conserve battery life.

TEST: Use the Up and Down buttons to choose test patterns. Used for troubleshooting device operation.

IMAGING (5)

The **IMAGING** button scrolls through the Image features. Use the **UP (6)** and **DOWN (7)** buttons to choose the level you want for each feature. The Image features are:

INTENSITY: Stimulation intensity control. Use the Up and Down buttons to increase or decrease (respectively) the intensity of the stimulation on your tongue. The device will beep at the limits of stimulation (highest = 100, lowest = 0). At power up, stimulation intensity always resets to zero and must be increased to your comfort level.

ZOOM: Camera field of view (FOV) control. Use the Up and Down buttons to zoom in (smaller FOV) or out (larger FOV). Press the Up button to increase the camera zoom level (reducing the camera's effective field of view). Press the Down button to decrease the camera zoom (increasing the camera's field of view). The device will beep at the limits of zoom (widest = 48 degrees, narrowest = 3 degrees).

INVERT: Invert the stimulation intensity values, where the strongest becomes the weakest and vice-versa. Use the Up and Down buttons to toggle between whether bright objects or dark objects in the field of view stimulate the tongue array.

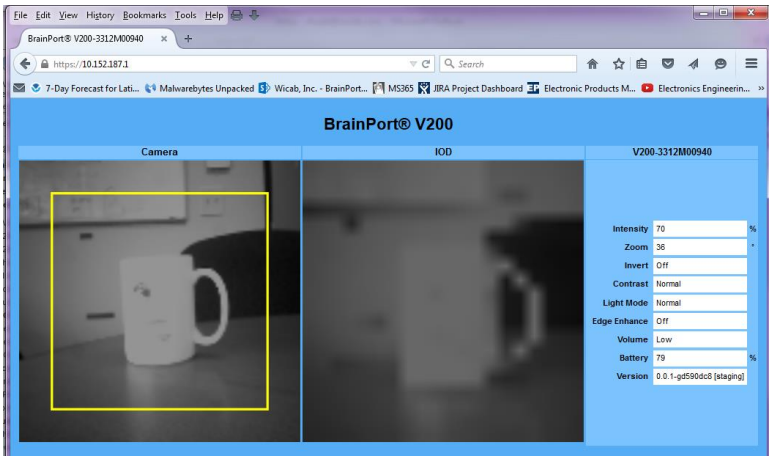
CONTRAST: Image contrast control. The Up and Down buttons toggle between normal contrast (default) and high contrast mode. High Contrast will enhance the difference between light and dark regions in the camera image.

EDGE ENHANCE: Enable/disable edge enhancement.
Use the Up and Down buttons to enable or disable this function. In this mode, edges in the camera image are enhanced to make them easier to distinguish.

CAMERA (8): The camera can be adjusted to point straight out from the headset or tilted down (to about 45 degrees) to reduce neck fatigue.

BATTERY CASE (NOT SHOWN): The battery case is attached at the rear of the V200 headset. Simple elastic straps are used to tighten or loosen the headset for comfort.

BrainPort V200 Companion View
A trainer or a sighted companion can use a web browser to view V200 camera images and basic status information. Using a MOBILE DEVICE with WiFi capability (laptop, tablet, or smartphone),



Specific Aim 2: Evaluate the safety and efficacy of the BrainPort V200 device on this population.

<u>Modifications to the BrainPort V200 Based on Subject Feedback</u>
Verbal user feedback was captured during the device training for initial subjects and as a result the following modifications have been implemented into the devices since the initial release:

- Audible feedback during power up/down was added
- The number of phrases used for verbal feedback was increased on the buttons to better explain the button options.

- The stimulation intensity range was modified so that the typical setting a user experiences interpretable stimulation is approximately 50%, rather than 85-100%.

What opportunities for training and professional development did the project provide?
Early in the recruitment process, the inclusion of veteran candidates appeared to be a challenge. Further networking efforts were initiated by the PI to engage the Jesse Brown VA Medical Center, which included exhibiting the BrainPort V100 at the Westside Institute for Science and Education Open House, "Celebrating VA Research", which helped to foster a collaboration between Wicab, Inc. and the Jesse Brown VA Medical Center.

How were the results disseminated to communities of interest?
The results of the study have not yet been disseminated to communities of interest since the first year of this project was dedicated to the development of the device and subject enrollment preparation. Over the next year we will determine which research conferences are most appropriate to disseminate our findings.

What do you plan to do during the next reporting period to accomplish the goals and objectives?
The main effort for the next reporting period is to enroll the remaining 11 subjects into the study, complete pre-post training assessments on all subjects, begin first quarterly functional evaluations for subjects enrolled in the 4th quarter of Year 1, continue mobile application interface development, and provide at least one mobile application to subjects during the first quarterly assessment period. The expected achievements for the next reporting period are detailed in Table 1.

Table 1. Scheduled achievements for Year 2- 1st Quarter

Major Task	SubTask
1. Human subject protocol and informed consent	• Coordinate with sites for the IRB continuing review submission.
2. Site Training	• Assure study staff has updated human subjects training for Year 2 of study
3. Participant Recruitment and Evaluation	• Enroll remaining subject to reach enrollment cap of 20. • Complete screening, training, and pre-post training assessments on all study subjects. • Complete 1st quarterly assessments on subjects enrolled during 4th quarter. • Distribute BrainPort V200 devices to all study participants during training.
4. Coordinate safety and efficacy reporting	• Monitor study data and communicate with study sites for reports of adverse events. • Monitor social networking website to review feedback from participants regarding device use.
5. Data Analysis	• Coordinate with sites and FITBIR to prepare case report forms to facilitate data share on FITBIR database • Coordinate with study sites to disseminate preliminary findings at the ARVO conference.

6. Review user feedback and modify hardware as necessary	• Continue to review study participant feedback and evaluate modifications of hardware implemented within the 4th quarter of Year 1.
7. Implement software modifications on a quarterly basis	• Provide mobile application to study subjects

4. IMPACT

There is nothing to report during this reporting period, as we early in the functional evaluation phase of the study.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change
Nothing to report to during this reporting period

Actual or anticipated problems or delays and actions or plans to resolve them
Nothing to report to during this reporting period

Changes that had a significant impact on expenditures
Nothing to report to during this reporting period

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to report to during this reporting period

6. PRODUCTS

Includes:

- The BrainPort V200 electronic vision aid (described previously) has been developed under this research activity. In calendar 2016 Wicab intends to apply to FDA and EU regulatory bodies for clearance to market the V200 in the US and EU.
- No inventions, patent applications, or licenses have resulted from this research.
- No other products were developed under this program

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Information for each person who has worked at least one person month per year on the project during the reporting year, regardless of compensation is outlined below.

1. Name: Patricia Grant
   Project Role: Co-PI: Lead Researcher
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 6
   Contribution to Project: Ms. Grant has been responsible for overseeing the conduct of the research to ensure consistent adherence to the study protocol across all sites. In addition,

she has been involved in subject recruitment and screening activities and has been responsible for obtaining and maintain IRB and HRPO approval.
Funding Support: N/A

2. Name: Rich Hogle
   Project Role: Co-PI – Lead Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 4
   Contribution to Project: Mr. Hogle has managed the activities of the Engineering team to ensure delivery of devices and associated software. As Lead Engineer, Mr. Hogle is responsible for the development of the BrainPort V200 from concept through release and support of devices for this research activity
   Funding Support: N/A

3. Name: Derald Woods
   Project Role: Software Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 8
   Contribution to Project: Mr. Woods has been responsible for the primary software development efforts related to BrainPort V200.
   Funding Support: N/A

4. Name: Ryan Pope
   Project Role: Production Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 1
   Contribution to Project: Mr. Pope has been involved with the BrainPort V200 builds, as well as the packaging and shipping activities involved with the V200 delivery to study sites.
   Funding Support: N/A

5. Name: Steve Correll
   Project Role: Electrical Engineer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 3
   Contribution to Project: Mr. Correll has been responsible for design and implementation of the electronic hardware architecture for BrainPort V200.
   Funding Support: N/A

6. Name: Janet Szlyk
   Project Role: Site PI
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 1
   Contribution to Project: Dr. Szlyk has been responsible for the conduct of the research at the Chicago Lighthouse. Including subject recruitment, device training, documentation, and all study-related procedures.
   Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02- 5.0 calendar months

7. Name: Meesa Maeng
   Project Role: Research Associate/BrainPort Trainer

Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Ms. Maeng has been responsible for all study-related procedures at the Chicago Lighthouse, including subject recruitment and screening, device training, and data collection.
Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 4.0 calendar months

8. Name: William Seiple
   Project Role: Site PI
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 2
   Contribution to Project: Dr. Seiple has been responsible for conduct of the research at the Lighthouse Guild. Including subject recruitment, device training, documentation, and all study-related procedures
   Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 5.0 calendar months

9. Name: Tiffany Arrango
   Project Role: Research Associate/BrainPort Trainer
   Researcher Identifier (e.g. ORCID ID): N/A
   Nearest person month worked: 3
   Contribution to Project: Ms. Arrango has been responsible for all study-related procedures at the Lighthouse Guild, including subject recruitment and screening, device training, and data collection.
   Funding Support: N/A

10. Name: Mike Oasen
    Project Role: Production Technician
    Researcher Identifier (e.g. ORCID ID): N/A
    Nearest person month worked: 2
    Contribution to Project: Mr. Oasen has contributed to the electronic hardware implementation as well as assisting in BrainPort V200 builds in support of this research activity.
    Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?
The partner organizations that have been involved in the project are detailed below.

Organization Name: The Chicago Lighthouse for People Who Are Blind and Visually Impaired
Location of Organization: Chicago, IL
Partner's contribution to the project (identify one or more): Facilities and collaboration (study site)

Organization Name: Lighthouse Guild
Location of Organization: New York, NY

Partner’s contribution to the project (identify one or more): Facilities and collaboration (study site)

8. SPECIAL REPORTING REQUIREMENTS

The Quad Chart for this reporting period is included in the Appendix.

9. APPENDIX

Appendix A: Quad Chart

APPENDIX A.

Safety and Efficacy of the BrainPort V200 Device in Individuals Blinded by Traumatic Injury

DM130076, Assistive Technologies Research Award

W81XWH-13-DMRDP-ATRA

PI: Patricia Grant, M.S. **Org:** Wicab, Inc. **Award Amount:** $1,393,819.84

Study/Product Aim(s)

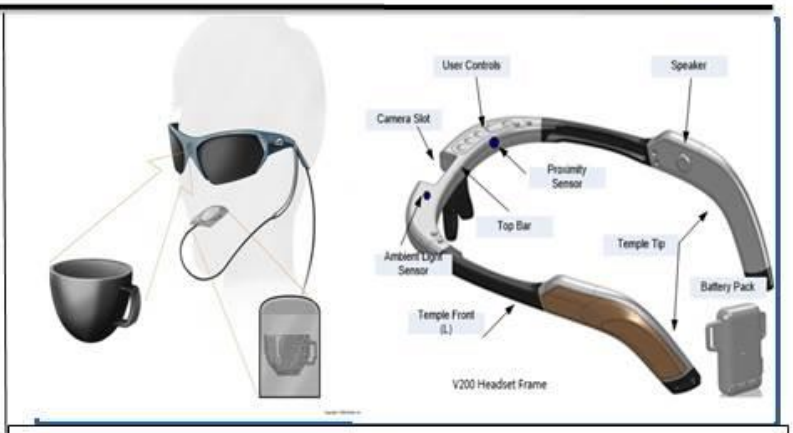
Aim1: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc.).

Aim 2: Evaluate the safety and efficacy of the BrainPort V200 device on this population.

Aim 3: Explore the design and hardware requirements for a population with multiple disabilities (polytrauma).

Approach

Twenty subjects who are profoundly blind due to a traumatic injury will be enrolled into the study. Subjects will receive approximately 10 hours of training in the clinic setting on the BrainPort V200 device and will then be sent home with the device for 12 months to use the device in their environments. Subjects will visit the study sites quarterly to complete efficacy and safety assessments.



The BrainPort device has demonstrated safety and efficacy in individuals blinded without cortical injury. The current research is designed to assess the safety and efficacy of the device in individuals blinded by traumatic injury (i.e. TBI or ocular trauma).

Timeline and Cost

Activities CY	14	15	16
Subject Recruitment			
Evaluation of device safety			
Evaluation of device efficacy			
Exploration of design requirements			
Estimated Budget ($K)	**$767**		**$627**

Updated: 10/23/2015

Goals/Milestones

CY14 Goal – Human subjects protocol and informed consent approval

- ☑ Finalize subject eligibility criteria and assessment measures
- ☑ NEIRB Approval

CY15 Goals – Study Site and Subject Training

- ☑ HRPO Approval
- ☐ Device hardware and software modifications implemented and evaluated
- ☐ Recruit and screen subjects
- ☐ BrainPort V200 devices and tablets distributed to subjects
- ☐ Subjects trained and pre-post training assessments completed
- ☐ Quarterly assessments evaluating safety and efficacy of device

CY16 Goal – Complete data collection, perform data analysis and reporting

- ☐ Quarterly assessments evaluating safety and efficacy of device
- ☐ Data analysis, report safety events and efficacy findings from study

Comments/Challenges/Issues/Concerns

- We are currently behind schedule in the enrollment of subjects due to the delay in the delivery date of the V200 devices last quarter. Approximately half of the subjects are currently enrolled and the remainder have been recruited. Enrollment of all subjects is expected to be complete within the next reporting period.

Budget Expenditure to Date

Projected Expenditure: $766,789.67

Actual Expenditure: 748,620.09